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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,220	05/17/2005	Juan Carlos Domingo Pedrol	OFI001-823324	9405

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WOLF BLOCK SCHORR AND SOLIS-COHEN LLP
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NEW YORK, NY 10177

EXAMINER

ZAREK, PAUL E

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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04/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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ADVISORY ACTION

1. Applicants traversed the rejection of claims 15-28 and requested Examiner to enter the amendments to the claims. After careful review, Examiner is not persuaded by Applicants' arguments and the proposed amendments will not be entered.
2. Claims 23 and 24 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it lacked antecedent basis. The claims recited the limitation that DHA is present in a concentration ranging from 5% to 100% by weight, or 50% to 100% by weight, which implies that they are part of a composition. Neither Claims 23 or 24, nor Claim 15, from which they depend, recite that DHA be administered as part of a composition. The amendments to Claims 23 and 24 do not overcome this rejection.
3. Claims 15-22, and 25-28 were rejected under 35 U.S.C. 102(e) as being anticipated by Pacioretty and Babish (US PreGrant Publication No. 2004/0106591, which claims the benefit of provisional application 60/428,246, filed on 11/22/2002). Claims 1, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacioretty and Babish (above). Applicants traversed these rejections on the grounds that this prior art requires the presence of a thiol-containing compound or trivalent chromium, and that this prior art administers the DHA after administration of HAART. Examiner respectfully disagrees. Instant Claim 16 (amended to be an independent claim) is drawn to a method for treating lipodystrophy comprising administration of DHA. "Comprising" is open language which allows for the presence of other components, such as a thiol-containing compound or trivalent chromium. Moreover, Pacioretty and Babish

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explicitly state that the HAART is continued during DHA administration (para 0084). The amendment to Claim 16 does not overcome these rejections.

4. Claims 15-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al. (Experimental and Clinical Endocrinology and Diabetes, 2001) in view of and Connor, et al. (Annals of the New York Academy of Sciences, 1993). Applicants traversed this rejection on the grounds that Examiner misinterpreted “lipodystrophy” and that hyperlipidemia and lipodystrophy are different clinical conditions. Examiner disagrees. Lipodystrophy is characterized by a defective metabolism of fat, a definition supported both by Stedman’s Medical Dictionary and Applicants. Moreover, hyperlipidemia is almost always associated with lipodystrophy, and lipodystrophy occurs in HIV patients receiving protease inhibitors (a component of HAART) (Bernasconi, The AIDS Reader, 1999, abstract). The amendment to Claim 16 does not overcome this rejection.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625